EXPRESS MAIL #EV656488943US

Application No.: PCT/AU2004/001456

Amendments to the Claims

This listing of claims will replace all prior versions, and listings of claims in the application. Please amend the claims as follows.

Please cancel claims 1-44. Please add new claims 45-66.

- 45. (New) A method for analyzing effector cell and/or regulator cell cycling to determine when an agent should be administered to a patient suffering from a disease characterized by the production of regulator cells, the method comprising monitoring the patient, or samples obtained therefrom, for at least one of: a) effector cell numbers and/or activity, b) regulator cell numbers and/or activity, c) a molecule associated with the disease, and/or d) an immune system marker.
- 46. (New) A method of treating a disease characterized by the production of regulator cells, the method comprising;
- i) analyzing effector cell and/or regulator cell cycling by monitoring a patient suffering from the disease for at least one of:
 - a) number and/or activity of regulator cells,
 - b) number and/or activity of effector cells,
 - c) a molecule associated with the disease, and/or
 - d) an immune system marker, and
- ii) exposing the patient to an agent to treat the disease, wherein the timing of administration of the agent is selected such that the activity of effector cells is not significantly reduced.

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- 47. (New) The method of claim 45, wherein the disease characterized by the production of regulator cells is cancer or an infection.
- 48. (New) The method of claim 45, wherein the patient is infected with HIV, Hepatitis B virus or Hepatitis C virus.
- 49. (New) The method of claim 45, wherein the immune system marker reflects the number and/or activity of regulator cells, and/or the number and/or activity of effector cells.
- 50. (New) The method of claim 45, wherein the immune system marker is an acute phase inflammatory marker.
- 51. (New) The method of claim 46, wherein the agent is administered between when the levels of an acute phase inflammatory marker have peaked and before the marker begins to rise in the next cycle.
- 52. (New) The method of claim 46, wherein the agent is administered about when CD4+CD8- T cells are detected.
- 53. (New) The method of claim 46, wherein the agent is administered approximately when CD8+CD4- T cell numbers have peaked.
- 54. (New) The method of claim 45, wherein the molecule associated with the disease is an antigen produced by a cancer cell or an infectious agent.
- 55. (New) The method of claim 46, wherein the agent is administered approximately when levels of the molecule associated with the disease begin to decrease.

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- 56. (New) The method of claim 45, wherein the patient is monitored for an acute phase inflammatory marker, and a molecule associated with the disease.
- 57. (New) The method of claim 46, wherein the agent is administered between when the levels of the acute phase inflammatory marker have peaked and before the marker begins to rise in the next cycle, and when levels of the molecule associated with the disease begin to decrease or would have been predicted to begin to decrease based upon previous analysis of the molecule.
- 58. (New) The method of claim 45, wherein the patient is monitored for a period of at least 21 days.
- 59. (New) The method of claim 45, the patient is monitored at least about every 3 days.
- 60. (New) The method of claim 45, wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.
- 61. (New) The method of claim 45, wherein the patient has not been exposed to a treatment for the disease for at least 21 days.
- 62. (New) The method of claim 45, wherein the patient is a human.
- 63. (New) A method for analyzing effector cell and/or regulator cell cycling to diagnose a disease characterized by the production of regulator cells, the method comprising monitoring the patient, or samples obtained therefrom, for at least one of: a) effector cell numbers and/or activity, b) regulator cell numbers and/or activity, c) a molecule associated with the disease, and/or d) an immune system marker, wherein cycling of any one of a) to d) indicates the disease may be present.

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- 64. (New) A method for analyzing effector cell and/or regulator cell cycling to determine when a vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells, the method comprising monitoring the patient, or samples obtained therefrom, for at least one of: a) effector cell numbers and/or activity, b) regulator cell numbers and/or activity, c) a molecule associated with the disease, and/or d) an immune system marker.
- 65. (New) A method of treating a disease characterized by the production of regulator cells, the method comprising;
- i) analyzing effector cell and/or regulator cell cycling by monitoring a patient suffering from the disease for at least one of:
 - a) number and/or activity of regulator cells,
 - b) number and/or activity of effector cells,
 - c) a molecule associated with the disease, and/or
 - d) an immune system marker, and
- ii) exposing the patient to an vaccine to treat the disease, wherein the timing of administration of the vaccine is selected such that the activity of effector cells is not significantly reduced.
- 66. (New) A kit when used for analyzing effector cell and/or regulator cell cycling to determine when an agent or vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells, the kit comprising at least one reagent for monitoring the patient, or samples obtained therefrom, for at least one of: a) effector cell numbers and/or activity, b) regulator cell numbers and/or activity, c) a molecule associated with the disease, and/or d) an immune system marker.